DEPARTMENT OF HEALTH
DIVISION OF FAMILY HEALTH
RHODE ISLAND IMMUNIZATION PROGRAM
PERFORMANCE AUDIT
SEPTEMBER 2004

DEPARTMENT OF ADMINISTRATION
BUREAU OF AUDITS
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STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

Department of Administration
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DEPARTMENT OF HEALTH
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EXECUTIVE SUMMARY

The Division of Family Health (DFH) is inadequately safeguarding and controlling their inventory management of vaccines as mandated by the Centers for Disease Control and Prevention (CDC). This is partly due to deficiencies in the CDC automated tracking system being used by DFH and in their procedures in issuing vaccines to providers by DFH's Vaccine Distribution Center.

The CDC requires the Department of Health (DOH) to make site visits to providers of state-supplied vaccines. There were several CDC compliance deficiencies in performing initial and follow-up site visits to providers by the DFH's Quality Assurance Staff. Included were incomplete questionnaire files of site visits and the lack of diligence in following up on provider deficiencies in their own storage, handling, and control of vaccines.

KIDSNET, a comprehensive children's services information system operated by DFH, serves as a data warehouse for medical providers to register a child's full medical immunization history. The DOH is presently attempting to expand the KIDSNET system to include a child's involvement in the supplemental nutrition program for Women, Infants and Children (WIC), lead screening, and information relating to KIDSNET site visits. The system is presently unable to generate reliable information between DOH and the providers. This is complicating DOH's attempt to create a single computerized program that encompasses a child's complete medical history.

DFH needs to continue their follow-up procedures on providers who are delinquent in filing their quarterly immunization data into the KIDSNET registry.

DFH does not have the state-mandated record control schedules for the custody, retention, destruction, and preservation of its public records.

DFH sponsors quarterly "Immunization Action Coalition" meetings that are not open to the general public. These meetings are subject to the "Open Meeting" state law that requires all such meetings be open to the general public.

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September 15, 2004

Patricia A. Nolan, M.D., Director
Department of Health
Three Capitol Hill
Providence, RI 02908

Dear Dr. Nolan:

We have completed our performance audit of the Department of Health, Division of Family Health, Infant-Child Immunization Program as of July 2003; where relevant, we extended our audit procedures to fiscal 2004. Our audit was conducted in accordance with Sections 35-7-3 and 35-7-4 of the Rhode Island General Laws.

The findings and recommendations included herein have been discussed with management and we have considered their comments in the preparation of the report. Management's response to our recommendations is included in this report.

In accordance with Section 35-7-4 of the Rhode Island General Laws, we will review the status of the Department of Health, Division of Family Health, Infant-Child Immunization Program's corrective action plan within six months from the date of issue of this report.

Sincerely,

H. Chris Der Vartanian, CPA
Chief, Bureau of Audits

HCD:pp

DEPARTMENT OF HEALTH
DIVISION OF FAMILY HEALTH
RHODE ISLAND IMMUNIZATION PROGRAM
PERFORMANCE AUDIT

INTRODUCTION

Objectives, Scope, and Methodology

We have conducted a performance audit of the Department of Health, Division of Family Health, Rhode Island Immunization Program for the fiscal year ended June 30, 2003 and the period July 1, 2003 to March 5, 2004. Our objectives were to evaluate the adequacy and effectiveness of managerial controls, the economy of resources, and compliance with significant laws and regulations applicable to the program. Our audit was made in accordance with *The Standards for the Professional Practice of Internal Auditing* issued by the Institute of Internal Auditing.

To accomplish our objectives, we obtained an understanding of the program operations to ascertain whether the results were consistent with the goals and objectives of the program and were carried out as planned. We also reviewed the reliability and integrity of financial and operational information. We interviewed responsible personnel and performed tests of the accounting records and other such auditing procedures, as we considered necessary in the circumstances.

The findings and recommendations included herein have been discussed with management, and we have considered their comments in the preparation of our report. Section 35-7-4 (c) of the Rhode Island General Laws requires the auditee to respond within 60 days to all recommendations in this report. Management's response to our findings and recommendations are included in this report.

Background

The Department of Health's Division of Family Health assesses and addresses the health and development needs of children and their families by developing comprehensive family-centered systems of care. The objectives of family health include, but are not limited to, preventing death, disease, and disability among children and encouraging life-long patterns of health behavior for all.

The Infant-Child Immunization Account is created within the Rhode Island General Fund as a restricted receipt account and is authorized under Section 23-1-45 of the Rhode Island General Law. Through this account the Department of Health funds those vaccines for routine childhood immunizations as recommended by the Advisory Committee for Immunization Practices and the Academy of Pediatrics.

In addition to childhood vaccinations, the Rhode Island Immunization Program includes Vaccine Management and Distribution, Surveillance of Vaccine – Preventable Diseases, Public and Provider Education, and Community Outreach. Through KIDSNET, a statewide public health tracking system, expert data, evaluations, and communications capacity support all family health programs.

FINDINGS AND RECOMMENDATIONS

VACCINES

Accountability: The Division of Family Health (DFH) orders all vaccines electronically through the Centers for Disease Control and Prevention (CDC) using the federal Vaccine Management Systems (VACMAN). All vaccine receipts and issuances are entered into the VACMAN. The Department of Health's (DOH) policies and procedures and CDC requires that monthly report of inventories be taken whereby quantities on hand are compared against the balances remaining (perpetual inventory) in the VACMAN.

We compared the actual count taken on September 30, 2003 and noted a significant number of discrepancies to the perpetual inventory generated by the VACMAN. DFH's Vaccine Distribution Specialist stated that these differences are the result of problems with the VACMAN software and also with the software's inability to be utilized in a network environment. These issues have prevented the timely and accurate input of receipt and distribution transactions into the VACMAN system. The Vaccine Distribution Specialist stated that a second inventory count is taken and the perpetual inventory is adjusted to reflect the balances on hand. This second inventory count is then forwarded to CDC. We were informed that an updated version of the VACMAN is currently being prepared that should improve the accuracy and operating efficiency of the system.

The inability of DFH to accurately track inventory of vaccines from month to month seriously impacts the safeguarding and control over vaccines. Vaccines having a short duration may go undistributed to physicians causing unnecessary spoilage, and although remote, unauthorized use becomes difficult to identify.

DOH's policies and procedures require all physicians to return expired/spoiled vaccines back to DFH where they are returned back to the manufacturer on a quarterly basis. In addition, an Expired/Spoiled Vaccine Report is also required to be prepared that accompanies the returned vaccines back to the manufacturers with a copy to be sent to CDC. Although DFH stated this report for the quarter ended December 31, 2003 was prepared and sent to CDC, no copy could be furnished to us.

Recommendations

1. Ensure that all receipts and distributions of vaccines are entered into the VACMAN for inventory control and safeguarding of vaccines.

   Management's Response: Accepted

2. Copies of Expired/Spoiled Vaccine Reports should be retained and filed for proper documentation.

   Management's Response: Accepted

Vaccine Distribution Center: DOH's policy and procedures require all requests for vaccines by providers be done using the Vaccine Order Form and be received at least one day prior to being picked up at the Vaccine Distribution Center (VDC). Each provider must furnish their Personal Identification Number (PIN) that identifies their facility on the form. The provider forwards a copy of their request to the VDC and retains the original. When the provider's agent picks up the vaccines, VDC personnel compare the provider's original copy to their received copy. Any changes to the quantities issued, along with an explanation, are made on the form. The provider's agent then dates and signs the form. The original copy is retained by DFH and the agent receives a copy.

We tested a sample of completed Vaccine Order Forms as well as observing several orders being distributed to provider agents. These efforts revealed the following:

- Instances where Vaccine Order Forms were filled out carelessly or incompletely (i.e. no PIN or inconsistencies between the request copy of the form to the form being represented at time of pick up).
- Instances where dosages per the initial order form did not agree with the amount distributed without adequate explanation.
- Different vaccine order forms were being used.
- Instances where provider agents who were unknown to VDC personnel were not asked to furnish proper identification.
- Informed that on rare occasions vaccine orders are taken over the telephone without a follow-up written request.

The above occurrences creates an environment that is deficient in adequate control and accuracy in issuing vaccines and may, in part, be contributing to the discrepancies in DFH's monthly inventory counts. The order forms should clearly provide for columns indicating amounts ordered and amounts actually filled; any differences between the two amounts should be adequately identified. The form presently does not provide for such information.

Recommendations

3. Ensure that all vaccines requests are in accordance with departmental policy and procedures and require that all provider agent's present proper identification.

   Management's Response: Accepted

4. Consider revising the Vaccine Order Form to provide columns for quantities ordered, and filled.

   Management's Response: Accepted

VFC/AFIX SITE VISITS

The CDC requires the DOH in administering the Rhode Island Immunization Program to make site visits to providers of state-supplied vaccines. These visits must assess vaccine storage, handling, and documentation for the federal Vaccines for Children (VFC) Program.

Beginning in 2002, the CDC mandated the Immunization Program to provide an opportunity to conduct review and staff discussions with individual medical practices as partners in **A**ssessment, **F**eedback, **I**ncentives, and **Ex**change (AFIX). During most VFC/AFIX site visits, a provider's immunization coverage levels are assessed. Questionnaires regarding vaccine management are also filled out during the visit. The provider and the VFC site team Quality Assurance Staff (QAS) evaluate data and discuss opportunities for immunizing children. The QAS will perform follow-up visits if findings resulting from the initial site review and follow-up phone calls could not resolve the issues.

As part of our audit we selected sample sizes of various types of site visits to test compliance with the CDC requirements. We randomly examined 7 of the 22 health center providers and 26 of the 78 private providers. We also examined 3 new provider practices and 4 follow-up visits.

Each site visit and follow-up visit is documented in a folder retained at the DOH. Our comparison of each selected site visit folder's documentation against the federal CDC requirements revealed the following:

- Documentation for 3 site visits could not be located.
- Only 2 folders contained a required Provider Visit Log.
- The VFC eligibility question was not answered on 3 of the Site Questionnaire Surveys.
- 16 provider folders did not contain a Problem Resolution Sheet and 14 contained an undated or unsigned Problem Resolution Sheet.
- 24 provider folders contained incomplete documentation (i.e., unanswered or poorly answered questions or contained information that appeared to be hastily written).

- All 4 follow-up folders did not contain adequate documentation to indicate that the folders were, in fact, follow-up visits. None of the questionnaires or other information referenced an original site visit. Further, there was no indication that the QAS was following up on original problems.

- The QAS indicated in 7 site visit folders that the providers examined had no internal written procedures concerning vaccine storage, handling, and inventory control. While the QAS documented this deficiency it did not indicate to the providers that this deficiency needed to be corrected promptly.

DOH management and the QAS cited time constraints imposed upon them due to staffing shortages as the cause for the above-stated deficiencies. In an effort to broaden their site visits, adherence to either federal requirements or to their own internal policies and procedures was not always followed. Notwithstanding these shortcomings, the DOH stated that they attempt to get private physicians to develop written policies and procedures surrounding vaccine inventory control. However, physicians have repeatedly stated they can never seem to devote sufficient time to develop their own policies and procedures over vaccine inventory management control.

Recommendations

5. Schedule all initial and follow-up site visits to adequately complete and document all requirements in accordance with CDC guidelines.

   Management's Response: Accepted

6. Consider the feasibility of creating effective vaccine inventory management and control procedures for the health care providers and disseminate the procedures to them.

   Management's Response: Accepted

CHILD IMMUNIZATION REPORT

Rhode Island General Law (RIGL) §23-1-46 requires the DOH to submit to the Rhode Island General Assembly by February 1 of each year a report on the child immunization program and the cost related to the program.

We were unable to secure a copy of this report. DOH stated that they were not sure if, in fact, the department prepared and submitted this report as required.

Recommendation

7. DOH needs to secure a file copy of the Child Immunization Report if one was submitted; otherwise immediately prepare and submit the report as required by statute.

Management's Response: Accepted

KIDSNET

The DOH operated a comprehensive children's services information registry called KIDSNET. This registry serves as a data warehouse for use by medical practices and school nurses. The KIDSNET registry contains a child's full medical immunization record. KIDSNET enrolls medical providers into the registry and provides them with training and equipment. The providers, in turn, enter weekly immunization activity data into KIDSNET.

All children born in Rhode Island since January 1, 1997, have been entered into the KIDSNET registry at birth by DOH's Office of Vital Records. If a child is not born in Rhode Island or was born before 1997 they may get into the system in one of two ways: if the child goes to a provider enrolled in KIDSNET, the provider will enter them or if the child qualifies for the WIC Program (supplemental nutrition program for Women, Infants and Children), they will be entered into the registry by the WIC personnel.

As of July 1, 2003, 87 providers in Rhode Island were active with KIDSNET. This represents more than half of all providers immunizing children under the age of six. It is expected by the beginning of 2005 that all providers will be enrolled, thereby ensuring that all children who go to a Rhode Island provider will have an accurate record of all their immunizations.

For the most part, the KIDSNET registry has met the Department's goals and objectives as outlined in their 2003 Immunization Grant Program application to CDC. However, as the registry continues to mature it has fallen short in the area of provider accountability. The immunization grant application indicated that at the end of fiscal 2003 greater than 90 percent of the providers utilizing KIDSNET for vaccine accountability would have had their data submitted and entered into the registry within 10 days of the end of each quarter.

Our audit showed that only 78 percent of the providers submitted the required data to KIDSNET within 10 days of the quarter ended December 31, 2003. Based on the data we received, we were unable to determine whether the Department followed up appropriately on the delinquent providers. KIDSNET personnel explained that they attempted to follow up sufficiently on data that is submitted late, either by a visit or a phone call to the providers. They stated, however, that sometimes they fall short because of staffing problems, time constraints, or other priorities.

Our audit further revealed that the computerized data system being used to keep track of all KIDSNET site visits is undergoing a major overhaul to link all health information so that immunizations, WIC, lead screening, and KIDSNET data can be accessed from one program. The DOH, at the time of this report, was not sure if an outside vendor would oversee the system update or whether it would be done by the Department's in-house information technology personnel.

In addition, the computerized data system presently in place is unable to provide reliable accounting of activity between DOH and their providers. DOH personnel have informed us that, even after utilizing electronic data along with manually-gathered data, they are still unable to supply accurate information. As a result, we did not test KIDSNET site visits due to the amount of time it would take for personnel to gather reliable information.

Recommendations

8. KIDSNET personnel should continue follow-up procedures on all providers who are delinquent in filing their quarterly immunization data into the registry and document the entire process.

   Management's Response: Accepted

9. Continue discussions with in-house information technology personnel concerning the upgrade of the computerized health information data system. Any enhancements to the system need to encompass all health data and provider site visit information that can be accessed efficiently through one program.

   Management's Response: Accepted

RECORDS MANAGEMENT

Rhode Island General Law §42-8.1-17 requires that each agency periodically communicate with the state archivist over the custody, retention and preservation of all public records. Further, RIGL's §38-1-10 and §38-3-6 require that each agency prepare and submit record control schedules to the Secretary of State, State Archives, for the protection, retention and final destruction of records in their custody. This approval process ensures that retention periods for all records will satisfy all legal, fiscal, administrative, and any historical necessity for all records generated by a state agency.

Our audit disclosed that the DFH does not have the required record control schedules over their public records, nor is there any documentation indicating that DFH has had any communication with the state archivist as required by the above-mentioned statutes. Management stated that only recently has DFH begun some verbal communication with the state archivist. Management added that immunization program priorities have taken precedence over this issue and therefore was not able to devote any effort towards records management.

Recommendation

10. Contact the state archivist to begin discussions for the preparation and submission of record control schedules in accordance with the above-mentioned state statutes.

Management's Response: Accepted

OPEN MEETINGS LAW

RIGL §42-46-3 requires that every meeting of a public body be open to the general public unless otherwise deemed closed, as provided for by RIGL's §42-46-4 and §42-46-5.

DFH, through its Immunization Program, sponsors quarterly "Immunization Action Coalition" (IAC) meetings. Members of the IAC are from business, government, community and public health, education, and community-based helping organizations. IAC members advise the Immunization Program on family needs and assist DFH in reaching families with information. The IAC meetings are closed to the general public. Since DFH has provided no basis precluding the general public from attending these meetings, they are being held in violation of the "Open Meeting" statute.

The public, by not having access to these meetings, are being deprived of potentially vital information as well as being denied the opportunity to voice their opinions or concerns. DFH stated that they were aware these meetings should be open to the public.

Recommendation

11. Ensure that all future IAC meetings are in compliance with the "Open Meeting" statute of the R.I. General Laws.

Management's Response: Accepted

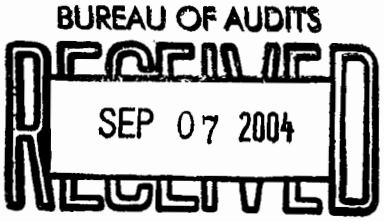
STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

D E P A R T M E N T O F H E A L T H

Safe and Healthy Lives in Safe and Healthy Communities

Patricia A. Nolan, MD, MPH
Director of Health

2 September 2004



H. Chris Der Vartanian, CPA
Chief, Bureau of Audits
RI Department of Administration
One Capitol Hill
Providence, RI 02908

Dear Mr. Der Vartanian:

Please find enclosed the response to the draft audit report of the Department of Health, Division of Family Health, Rhode Island Immunization Program for the fiscal year ended June 30, 2003, and the period July 1, 2003 to March 5, 2004.

We appreciate the revisions in the areas of concern we raised at our exit conference on July 15th. We especially appreciate the time taken by the staff at the Bureau of Audits and the Acting Chief, Frank J. Collaro, Jr., to understand the points of discussion for such a complex program.

We believe all recommendations are now stated in a manner that more closely reflects the points raised, and in fact we unequivocally accept all recommendations.

We would appreciate, if possible, that the first sentence of the Executive Summary include the word "management" after the word inventory, as discussed at the meeting.

Once again, we thank the staff involved for their thoroughness and courtesy during the entire audit process.

Sincerely,

Patricia A. Nolan, MD, MPH

Patricia A. Nolan, MD, MPH
Director of Health

PAN:bjs

Enclosure (1)

DEPARTMENT OF HEALTH
DIVISON OF FAMILY HEALTH-RI
RHODE ISLAND IMMUNIZAZITON PROGRAM
PERFORMANCE AUDIT

FINDINGS AND RECOMMENDATIONS

VACCINES

Recommendations

1. Ensure that all receipts and distributions are entered into the VACMAN for inventory control and safeguarding of Vaccines.

Response

Accepted. The new version 3.0 of VACMAN was installed in May 2004. All appropriate staff has received training by the CDC and the system has been up and operational since mid May 2004.

2. Copies of Expired/Spoiled Vaccine Reports should be retained and filed for proper documentation.

Response

Accepted. All reports are filed quarterly and will be retained in accordance with HEALTH's records retention schedule.

VACCINE DISTRIBUTION CENTER

Recommendations

3. Ensure that all vaccines requests are in accordance with departmental policy and procedures and require that all provider agents present proper identification.

Response

Accepted. All agents presenting to the HEALTH wholesale distribution center are now required to present proper identification when requesting supplies.

4. Consider revising the Vaccine Order Form to provide columns for quantities ordered, and filled.

Response

Accepted. Forms have been adjusted to show consistency and past forms, although still often sent by providers, are no longer being accepted.

VFC/AFIX SITE VISITS

Recommendations

5. Schedule all initial and follow-up site visits to adequately complete and document all requirements in accordance with CDC guidelines.

Response

Accepted. All staff has received updated training in site visit requirements. The team manager for VFC/AFIX is working closely with site visit staff to ensure adequate time management and full follow up and documentation in accordance with CDC guidelines.

6. Consider the feasibility of creating effective vaccine inventory and control and management procedures for the health care providers and disseminate the procedures to them.

Response

Accepted. The Immunization Program is utilizing CDC documents and adapting them for the use of Rhode Island providers. These procedural documents will be provided to every medical practice that newly or re-enrolls with the state supplied vaccine program for 2005.

CHILD IMMUNIZATION REPORT

Recommendation

7. DOH needs to secure a file copy of the Child Immunization Report if one was submitted; otherwise immediately prepare and submit the report as required by statute.

Response

Accepted. Due to the departure of the former chief budget officer, the DOH was unable to locate the file copy of this report. Therefore, a new report has been prepared and will be submitted to the General Assembly. Procedures are now in place to ensure the report copy is in a central location.

KIDSNET

Recommendation

8. KIDSNET personnel should continue follow up procedures on all providers who are delinquent in filing their quarterly immunization data into the registry and document the entire process.

Response

Accepted. Beginning January 1, the Immunization and KIDSNET programs have agreed upon a collaboration that would require monthly reporting for vaccine approval. KIDSNET provider relations staff are working closely with traditionally delinquent providers to assist them in preparing for this change, and are documenting all contacts.

9. Continue discussions with in-house information technology personnel concerning the upgrade of the computerized health information data system. Any enhancements to the system need to encompass all health data and provider site visit information that can be accessed efficiently through one program.

Response

Accepted. This effort is ongoing under the leadership of Amy Zimmerman, chief of Children's Preventive Services, and Bob Childs, chief of Management Information Services.

RECORDS MANAGEMENT

Recommendation

10. Contact the state archivist to begin discussions for the preparation and submission of record control schedules in accordance with the General Law statutes.

Response

Accepted. This contact was made and all key staff have received the first level of training. Draft documents were submitted for review and the department will finalize the schedule as soon as possible.

OPEN MEETINGS LAW

Recommendation

11. Ensure that all future IAC meetings are in compliance with the "Open Meeting" statute of the R.I. General Laws.

Response

Accepted. Key HEALTH staff have received the first in a series of trainings on open meetings statutes and all community meetings and coalitions have been reviewed for necessary compliance. The IAC, as a coalition that must be in compliance, will post all meetings as required by the statute.